UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CAMPAIGN FOR RESPONSIBLE TRANSPLANTATION,

Plaintiff,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION,

Defendant,

and

CIRCE BIOMEDICAL, INC. *et al.*,

Defendant-Intervenors.

Civil Action No.: 00-2849 (RMU)

Document Nos.: 58, 62

MEMORANDUM OPINION

GRANTING IN PART AND DENYING IN PART THE PLAINTIFF'S AND DEFENDANT'S MOTIONS FOR SUMMARY JUDGMENT

I. INTRODUCTION

Xenotransplantation involves the implantation of live animal tissues, cells and organs into human beings for the treatment of human diseases. The plaintiff, Campaign for Responsible Transplantation ("CRT"), a non-profit organization dedicated to educating the public about the health risks associated with xenotransplantation, brings this action pursuant to the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552 *et seq.*, to compel the defendant, United States Food and Drug Administration ("FDA"), to disclose various records concerning xenotransplantation. Concerned that their investigational new drugs

("INDs") may fall within the scope of CRT's FOIA request, six biotechnology companies intervened.

This matter is before the court on the plaintiff's and the defendant's motions for summary judgment. Four of the six defendant-intervenors—Circe Biomedical, Inc. ("Circe"); Nextran, Inc. ("Nextran"); Diacrin, Inc. ("Diacrin"); and Diacrin/Genzyme LLC ("Diacrin/Genzyme")—oppose the plaintiff's motion and support the defendant's motion for summary judgment. Novartis Pharmaceuticals Corporation ("Novartis") filed a response asking for a clarification of the plaintiff's request.[1]

For the reasons that follow, the court grants in part and denies in part both parties' motions for summary judgment. The court also orders FDA to resubmit new sample *Vaughn* indices[2] consistent with this memorandum opinion.

II. BACKGROUND

Xenotransplantation involves the introduction of animal cells, tissues and organs into the human body to replace parts of the body damaged by disease. Pl.'s Mot. for Summ. J. at 3. CRT's concerns about xenotransplantation stem from the risk of cross-species viral infections[3] within animal tissue. *Id.* at 6. Numerous cross-species viruses, including human immunodeficiency virus, Creutzfeldt-Jacob (mad cow) disease, Ebola, Hanta virus, rabies, and influenza, already exist outside of xenotransplantation. *Id.* Ex. E at 3. Since pigs are

[1] FDA did not include records relevant to Novartis' INDs in the sample *Vaughn* index. *Campaign for Responsible Transplantation v. Food & Drug Admin.*, 180 F. Supp. 2d 29, 34 (D.D.C. 2001) (denying the plaintiff's motion for a comprehensive *Vaughn* index and granting the defendant's motion for a representative *Vaughn* index); Novartis' Response at n.2.

[2] A *Vaughn* index is an affidavit that specifically describes withheld or redacted documents and justifies why each withheld record is exempt from disclosure. *Vaughn v. Rosen*, 484 F.2d 820, 826-28 (D.C. Cir. 1973); *King v. Dep't of Justice*, 830 F.2d 210, 218-19 (D.C. Cir. 1987).

[3] A cross-species virus is a virus that can infect multiple animal species and humans. Pl.'s Mot. for Summ. J. at 6.

the animal most commonly used in xenotransplantation, CRT is particularly concerned with cross-species viruses that are dormant in pigs but could be dangerous for humans. *Id.* at 6. Known as porcine endogenous retroviruses ("PERV"), these cross-species viruses exist within the DNA of pig cells. *Id.*

FDA currently regulates xenotransplantation products as INDs and "biological products" under section 351 of the Public Health Service Act, 42 U.S.C. § 262, the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321 *et seq.*, and various other FDA regulations, *e.g.* 21 C.F.R. § 312 *et seq.*; 21 C.F.R. § 601 *et seq*. FDA is also responsible for reviewing applications by pharmaceutical and biotechnology companies that conduct human clinical trials involving xenotransplantation. Compl. ¶ 6. According to the plaintiff, FDA routinely grants approval for these trials "without any further federal oversight regarding health and ethical considerations—despite the Department of Health and Human Services' acknowledgment that 'concerns have arisen in the last few years about the potential infection, disease and public health risks associated with xenotransplantation.'" *Id.* (citing 64 Fed. Reg. 73562 (Dec. 30, 1999)).

On March 9, 2000, CRT submitted a written FOIA request to FDA for all records concerning clinical trials that involved xenotransplantation. *Id.* ¶ 7. By letter dated March 14, 2000, FDA acknowledged receipt of CRT's request and indicated that it would respond to the request "as soon as possible." *Id.* ¶ 9. When CRT did not receive a response by August 2, 2000, CRT appealed the constructive denial of its FOIA request to FDA. *Id.* ¶ 10. After FDA failed to respond to the appeal, CRT filed suit in this court on November 27, 2000 to compel immediate disclosure of the requested records. *Id.* On March 1, 2001, the court granted motions by Genezyme Corporation ("Genezyme"), Circe, Diacrin,

Diacrin/Genezyme, Nextran and Norvartis to intervene in this case. Order dated Mar. 1, 2001.

In its original FOIA request, CRT sought "all FDA records concerning applications for approval to conduct clinical trials in humans that involve xenotransplantation, and all information concerning currently ongoing and concluded clinical trials involving xenotransplantation." *Id.* ¶ 7. The original FOIA request included information previously submitted to FDA by third parties, including the defendant-intervenors. *Id.* In this action, CRT narrowed its original request to include only those documents generated by FDA. Pl.'s Mot. for Summ. J. at 21. CRT then moved for a *Vaughn* index of documents that FDA still withheld. *Id.* at 22. The court denied CRT's motion and granted FDA's motion to produce a representative sample *Vaughn* index of one IND.[4] *Campaign,* 180 F. Supp 2d at 34. In response, FDA produced two *Vaughn* indices, one pertaining to clinical trials ("Clinical Trials *Vaughn* Index") and one pertaining to IND "G" ("IND "G" *Vaughn* Index"), the IND that CRT picked. Pl.'s Mot. for Summ. J. at 22. The plaintiff and the defendant now both move for summary judgment. Four defendant-intervenors oppose the plaintiff's motion and one has filed a request for clarification. Since January 15, 2002, when the plaintiff filed for summary judgment, FDA has filed Third, Fourth, and Fifth declarations to supplement the original two *Vaughn* indices.

[4] In this case, each of the 35 INDs contains an average of 7,000 pages of documents, totaling over 240,000 pages of documents that FDA would have to review for a comprehensive *Vaughn* index. *Campaign*, 180 F. Supp. 2d at 34. FDA moved to compile a representative sample *Vaughn* index because a comprehensive *Vaughn* index would have taken more than two years to compile. *Id*. at 31. Any references to FDA's *Vaughn* indices refer to the two representative sample *Vaughn* indices submitted by FDA.

III. ANALYSIS

A. Legal Standard for Summary Judgment in a FOIA-Review Case

Summary judgment is appropriate when "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." FED. R. CIV. P. 56(c); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986); *Diamond v. Atwood*, 43 F.3d 1538, 1540 (D.C. Cir. 1995). To determine which facts are "material," a court must look to the substantive law on which each claim rests. *Anderson v. Liberty Lobby, Inc*., 477 U.S. 242, 248 (1986). A "genuine issue" is one whose resolution could establish an element of a claim or defense and, therefore, affect the outcome of the action. *Celotex*, 477 U.S. at 322; *Anderson*, 477 U.S. at 248. In ruling on a motion for summary judgment, the court must draw all justifiable inferences in the nonmoving party's favor and accept the nonmoving party's evidence as true. *Anderson*, 477 U.S. at 255.

FOIA affords the public access to virtually any federal government record that FOIA itself does not specifically exempt from disclosure. 5 U.S.C. § 552; *Vaughn*, 484 F.2d at 823. FOIA confers jurisdiction on the federal district courts to order the release of improperly withheld or redacted information. 5 U.S.C § 552(a)(4)(B). In a judicial review of an agency's response to a FOIA request, the defendant agency has the burden of justifying nondisclosure, and the court reviews *de novo* the agency's action. 5 U.S.C. § 552(a)(4)(B); *Al-Fayed v. CIA*, 254 F.3d 300, 305 (D.C. Cir. 2001). The court may grant summary judgment to an agency on the basis of its affidavits if they (a) "describe the documents and the justifications for nondisclosure with reasonably specific detail," (b)

"demonstrate that the information withheld logically falls within the claimed exemption," and (c) "are not controverted by either contrary evidence in the record nor by evidence of agency bad faith." *Military Audit Project v. Casey*, 656 F.2d 724, 738 (D.C. Cir. 1981). While an agency's affidavits are presumed to be in good faith, a plaintiff can rebut this presumption with evidence of bad faith. *Ground Saucer Watch, Inc. v. CIA*, 692 F.2d 770, 771 (D.C. Cir. 1981). But such evidence cannot be comprised of "purely speculative claims about the existence and discoverability of other documents." *Id.*

B. FDA's Search for Documents Relating to CRT's Request Was Reasonable

1. Legal Standard for a Reasonable Search

An agency must respond to FOIA requests by conducting a search that is reasonably calculated to uncover all of the relevant documents. *Steinberg v. Dep't of Justice*, 23 F.3d 548, 551 (D.C. Cir. 1994). To conduct an adequate search, the agency must search for documents in good faith, using methods that are reasonably expected to produce the information requested. *Oglesby v. Dep't of Army*, 920 F.2d 57, 68 (D.C. Cir. 1990) ("*Oglesby I*"); *Campbell v. Dep't of Justice*, 164 F.3d 20, 27 (D.C. Cir. 1998). The agency need not search every record system or conduct a perfect search. *SafeCard Am. Servs., Inc. v. SEC*, 926 F.2d 1197, 1201 (D.C. Cir. 1991); *Meeropol v. Meese*, 790 F.2d 942, 952, 956 (D.C. Cir. 1986). Nevertheless, the government must demonstrate that the search was "reasonably calculated to uncover all relevant documents." *Weisberg v. Dep't of Justice*, 705 F.2d 1344, 1351 (D.C. Cir. 1983) ("*Weisberg I*"). To demonstrate reasonableness, an agency must set forth sufficient information in affidavits for the court to determine, based on the facts of the case, that the search was reasonable. *Id.* at 1350-51; *Oglesby I*, 920 F.2d at 68.

2. The FDA's Search was Reasonable

The plaintiff claims that FDA has not conducted a reasonable search because important documents are missing from the *Vaughn* indices and because a supplementary FDA search revealed more documents. Pl.'s Mot. for Summ. J. at 44. The court determines, however, that FDA has provided ample evidence to prove that FDA conducted a reasonable search. *Weisberg I,* 705 F.2d at 1351.

FDA's original search encompassed all 21 divisions of the Center for Biologics Evaluation and Research ("CBER"), the section responsible for regulating xenotransplantation. 4th Banks Decl. at 11. In addition to searching CBER, FDA also searched the Office of the Commissioner and Office of Regulatory Affairs and found no relevant documents within those departments. 5th Banks Decl. ¶ 11. FDA explained that many of the documents that the plaintiff argued were missing from the *Vaughn* indices actually were listed within the indices, but required further description in a supplementary declaration, provided by FDA.[5] Def.'s Cross-Mot. for Summ. J. at 12-14, Ex. N.

According to the plaintiff's own estimates, this particular FOIA request involves almost 27,000 documents consisting of over 240,000 pages. Pl.'s Mot. for Summ. J. at 23, n. 14; *Campaign*, 180 F. Supp. 2d at 34; Def.'s Reply at 19. FDA has released hundreds of pages of documents to the plaintiff. Def.'s Statement of Material Facts ¶¶ 44, 50, 51, 53. After the plaintiff filed its motion for summary judgment, providing further details regarding the documents it seeks, FDA produced 55 additional documents. Def.'s Reply at 15. In light of the voluminous number of documents relevant to this FOIA request, the addition of 55 documents is a proverbial "drop in the bucket." Rather than serving as proof that FDA

[5] The fact that plaintiff could not determine whether the documents relating to certain events were within FDA's *Vaughn* index suggests that the *Vaughn* index could be inadequate. Part III.C *infra.*

had failed to search adequately, FDA utilized new information to find a few more documents. FDA is only required to conduct a reasonable search, which does not entail finding *all* relevant documents. *Meeropol*, 790 F.2d at 952-53.

The fundamental question is whether the search for responsive documents was reasonable and thereby adequate, not whether any other responsive documents may possibly exist. *Steinberg*, 23 F.3d at 551 (citing *Weisberg v. Dep't of Justice*, 745 F.2d 1476, 1485 (D.C. Cir. 1984) ("*Weisberg II*")). In this case, FDA has indicated through numerous affidavits its exact search methods. *See e.g.*, 4th Banks Decl.; 2d Frey Decl.; 5th Banks Decl. The plaintiff has not disputed any of these affidavits. These affidavits are entitled to a good-faith presumption unless the plaintiff rebuts the presumption with evidence of bad faith. *Ground Saucer Watch*, 692 F.2d at 771. Thus, FDA has met its burden to demonstrate that it conducted a reasonable search to find all responsive documents. *Weisberg I*, 705 F.2d at 1351.

C. FDA's *Vaughn* Indices Are Inadequate and FDA Must Submit A New Index for ING "G" and a New Index for the Clinical Trials

1. Legal Standard for the Adequacy of a *Vaughn* Index

In FOIA cases, the requester is often unable to argue for the release of redacted or withheld documents with "desirable legal precision" because "the party seeking disclosure cannot know the precise contents of the documents sought." *Vaughn*, 484 F.2d at 823. To prevent courts from having to review hundreds or thousands of documents *in camera*, the D.C. Circuit set forth special procedures—the filing of a *Vaughn* index—to assist both courts and requesters in reviewing the validity of an agency's decision to withhold documents. *Vaughn*, 484 F.2d at 826-28. A *Vaughn* index is an affidavit that indexes and specifically describes withheld or redacted documents and explains why each withheld

record is exempt from disclosure. *King*, 830 F.2d at 219. The index must "afford the FOIA requester a meaningful opportunity to contest, and the district court an adequate foundation to review, the soundness of the withholding." *King*, 839 F.2d at 218.

Toward that end, the requester and the trial judge must "be able to derive from the [*Vaughn*] index a clear explanation of why each document or portion of a document withheld is putatively exempt from disclosure." *Judicial Watch, Inc. v. Export-Import Bank*, 108 F. Supp. 2d 19, 34 (D.D.C. 2000) (quoting *Jones v. FBI*, 41 F.3d 238, 242 (6th Cir. 1994)). While there is no set form for a *Vaughn* index, the agency should describe the documents with "as much information as possible without thwarting the exemption's purpose." *King*, 830 F.2d at 224. Moreover, a *Vaughn* index must provide "a relatively detailed justification, *specifically identifying the reasons why* a particular exemption is relevant and correlating those claims with the particular part of a withheld document to which they apply." *Mead Data Cent., Inc. v. Dep't of Air Force*, 566 F.2d 242, 251 (D.C. Cir. 1977) (emphasis added). In *Founding Church of Scientology*, the D.C. Circuit noted three important elements for an adequate *Vaughn* index: (1) the index should be one document, (2) the index must adequately describe the withheld documents or deletions, (3) the index must state the particular FOIA exemption, and explain why the exemption applies. 603 F.2d at 949. Finally, the index should also note if the agency has segregated any discloseable information from each withheld document. *Vaughn*, 484 F.2d at 827.

2. FDA's *Vaughn* Indices Are Inadequate

FDA's sample *Vaughn* indices are inadequate because they fail to provide the information required by *Vaughn* and its progeny. *Vaughn*, 484 F.2d at 823. Both of these indices contain the following information: document number, page or paragraph range

withheld, description, reason for withholding, authority, and a cross-reference to an affidavit explaining the records. 2d Banks Decl. ¶ 7; IND "G" *Vaughn* Index; Clinical Trials *Vaughn* Index. The description, reason for withholding, and cross-references do not provide enough information to give this court and the requester a clear indication of the justification for each exemption. *King*, 839 F.2d at 218.

Within each representative index, the defendant's descriptions of the documents consist of the subject headings or titles of the documents. Def.'s Cross-Mot. for Summ. J. at 16. The subject headings and titles of the documents are short and simple. IND "G" Vaughn Index; Clinical Trials Vaughn Index. For instance, FDA lists documents 200, 935, 1065, and 1179 simply as "Internal Memo RE: Xeno." *Id.* These short descriptions would be sufficient if they actually provide a "functional description of the documents . . . ." *Oglesby v. Dep't of the Army*, 79 F.3d 1172, 1184 (D.C. Cir. 1996) ("*Oglesby II*"). They do not. Rather, many of the descriptions only provide a vague hint at the possible contents of the documents. This type of description does not give the court or the requester the necessary functional description of the documents at issue. *Id.*

Providing another example of the inadequacy of the *Vaughn* indices, the plaintiff argues that FDA neither released documents pertaining to, nor did it describe in its *Vaughn* indices, information that the plaintiff believes FDA possesses regarding the 1997 suspension and the 1998 resumption of certain clinical trials.[6] Pl.'s Mot. for Summ. J. at 44; Part III.B.2

[6] In March 1997, Clive Patience, Yasuhiro Takeuchi and Robin A. Weiss published an experiment in Nature Medicine in which two PERVs infected human cells. Pl.'s Mot. for Summ. J. Ex. I (Clive Patience, Yasuhiro Takeuchi and Robin A. Weiss, *Infection of Human Cells by an Endogenous Retrovirus of Pigs*, 3 Nature Medicine 282, 283-284 (March 1997)), Ex. P. As this information about PERVs surfaced, FDA suspended all xenotransplantation clinical trials using pigs on October 16, 1997 until sponsors developed assays on preclinical detection of PERVs, post-xenotransplant screenings for PERVs, and informed consent documents indicating the risks of PERV infection. Pl.'s Mot. for Summ. J. at 44, Ex. A at 7. FDA allowed trials to resume in 1998. *Id*. at 44.

supra. FDA responded by providing declarations stating that the requested information is described in the IND "G" *Vaughn* Index descriptions for documents 156, 181, 345-46, 353, 393, 738 and 763 and in the Clinical Trials *Vaughn* Index descriptions for documents 323, 736, 826-27. Def.'s Cross-Mot. for Summ. J. at 12. FDA's *Vaughn* indices describe these documents as follows:

***Vaughn* Indices**	
Docum	**Index Description**
156	**IND G:** 11/26/97 Clinical Trial Outline
181	**IND G:** 11/18/97 Telecon with sponsor an CBER re: sponsor Request for Amendment with handwritten notes from an unknown reviewer
323	**Clinical Trial:** Internal E-Mails on same page: 3/10/99, 3/4/99, RE: pig retrovirus question
345	**IND G:** 10/16/97 Letter to: sponsor from: CBER
346	**IND G:** 3/12/98 Letter to: sponsor from: author unknown
353	**IND G:** 11/25/97 Author unknown document re Clinical Trial
393	**IND G:** Undated summary of Clinical Hold Issues
736	**Clinical Trial**: Undated draft letter to Porcine Xenograft IND review teams re letter to be sent to sponsors
738	**IND G:** 3/12/98 Letter re: xenotransplant cells w/reference to previous telecom
763	**IND G:** 11/18/97 Internal Telecon with sponsor
826	**Clinical Trial:** 9/2/98, Agenda, RE: CBER Xenotransplantation Action Plan
827	**Clinical Trial**: undated, Algorithm, RE: Xenotransplantation patient monitoring algorithm

IND "G" *Vaughn* Index; Clinical Trial *Vaughn* Index; *see also* Pl.'s Reply Ex. UU.

None of the descriptions give the court or the requester sufficient information to discern that these particular documents refer to the suspension or reinstatement of the clinical trials. The only reason that the court and the plaintiff know these particular documents refer to the suspension and reinstatement of the clinical trials is that FDA submitted a supplementary declaration describing the documents in question in greater detail. Def.'s Cross-Mot. for

Summ. J. at 12-14; 4th Banks Decl. ¶¶ 4-6. By having to supply a declaration to explain further to the court and the plaintiff that the documents relating to the clinical trials are in fact already noted in the *Vaughn* indices, the defendant effectively demonstrates that its indices are inadequate.

In addition, the plaintiff contends that no document released or noted within the indices referred to the development of assays for minimizing the risk of PERV infections or to the 232 adverse events that occurred during the clinical testing of a new xenotransplant product, NeuroCell-PD, by Diacrin.[7] Pl.'s Mot. for Summ. J. at 44, Ex. A at 7, Ex. C at 113-14. FDA clarified, again through a supplemental affidavit submitted after the submission of the *Vaughn* indices, that the documents were already in the *Vaughn* indices.[8] 4th Bank Declaration ¶¶ 4-6.

Generally, the defendant's descriptions use vague terms that do not describe the content of the actual documents in question. IND "G" Vaughn Index; Clinical Trials Vaughn Index. For example, the description "Internal Memo RE: Xeno" actually represents a bevy of documents that deal with topics ranging from "'scientific' information regarding the use of non-human primates in xenotransplantation" to simply "patient experiments."[9] Pl.'s Reply at 7, Ex. UU. While there is no set format for a functional index, the *Vaughn*

[7] NeuroCell-PD is a xenotransplant product developed in a joint venture between Diacrin and Genzyme involving the implantation of pig neural cells in order to combat nervous system diseases. Pl.'s Mot. for Summ. J. Ex. V at 2-3. NeuroCell-PD clinical trials have not reported any PERV infections. *Id.* at 3.

[8] The plaintiff further notes 59 documents for which FDA had to supplement the descriptions in the indices in order to justify their withholding. Pl.'s Reply Ex. UU.

[9] The description "Internal Memo RE: Xeno" is not the only vague and puzzling description. Some other examples are descriptions such as "IND G: Undated Internal Memo re: Testing" (Document 28), "IND G: 10/7/99 Memorandum to File" (Document 130), "IND G: Letter, sent approximately on 10/24/94" (Document 149), "IND G: 2/23/99, Internal E-mail, RE: response to E-mail" (Document 168), "IND G: 7/16/98, Internal E-mail" (Document 190), "IND G: Undated typed notes from response re: various issues" (Document 194), and "General: undated, Review, RE: Master File" (Document 2991). IND "G" *Vaughn* Index; Clinical Trial *Vaughn* Index; *see also* Pl.'s Mot. for Summ. J. at Ex. LL.

index must provide as much information as possible without defeating the purpose of the exemption. *King*, 830 F.2d at 224. The court concludes that FDA's indices fail to provide a basic functional description of many of the documents. *Oglesby II*, 79 F.3d at 1184.

Turning to the second flaw with FDA's indices, the court explains why the FDA's listed reasons for withholding documents are deficient. 2d Banks Decl. ¶ 7; IND "G" *Vaughn* Index; Clinical Trials *Vaughn* Index. Within its *Vaughn* indices, FDA provides its reasons for withholding documents in column format. *Id.* In the column indicating the reasons for withholding, FDA uses only terms from the general legal standard for the relevant FOIA exemptions. CRT claims that repeating the legal standard in this method makes the *Vaughn* indices inadequate. Pl.'s Mot. for Summ. J. at 32, 35, 39. Opposing this argument, FDA cites as authority for its actions *Landmark Legal Foundation v. IRS*, where the court allowed the Internal Revenue Service to repeat verbatim language from a statute as the reason for withholding a document in a *Vaughn* index. 267 F.3d 1132, 1138 (D.C. Cir. 2001). The case at bar, however, is distinguishable from *Landmark Legal Foundation*. The *Vaughn* index in *Landmark Legal Foundation* contained individualized descriptions of the documents that correlated with the repetitive statutory language and thereby fulfilled the purpose of the *Vaughn* index: "[to] be able to derive . . . a clear explanation of why each document or portion of a document withheld is putatively exempt from disclosure." *Judicial Watch*, 108 F. Supp. 2d at 34 (quoting *Jones*, 41 F. 3d at 242); *Landmark Legal Foundation*, 267 F.3d at 1138. Within FDA's *Vaughn* indices, however, no individualized descriptions exist. FDA's descriptions of the documents give only the subject heading or title and provide no other information. Pl.'s Mot. for Summ. J. at 16. These descriptions combined

with a brief legal standard do not provide the required "clear explanation." *Judicial Watch*, 108 F. Supp. 2d at 34 (quoting *Jones*, 41 F.3d at 242).

Having discussed the index's descriptions of documents and statements of reasons for withholding, the court now addresses the index's cross-references. Even with the cross-references to the Second Banks Declaration, the defendant's *Vaughn* indices are inadequate. Though this is not dispositive by itself, the cross-references violate the D.C. Circuit's requirement that the index be one complete document. *Founding Church of Scientology*, 603 F.2d at 949. Furthermore, many of the cross-references provide only vague conclusory statements that repeat the reasoning for withholding the document, but never precisely relate to the descriptions of the documents in the *Vaughn* indices.[10] *King*, 830 F.2d at 219, 224.

[10] For example, paragraph nine and ten of the Second Banks Declaration, which are the most frequently quoted in the *Vaughn* index, state:

> 9. Exemption 4 protects "trade secrets and commercial or financial information obtained from a person and privileged or confidential. 5 U.S.C. § 552(b)(4). The documents in the *Vaughn* Index for which ALFOI has asserted Exemption 4 are protected because they contain trade secret and/or confidential commercial information. The release of this information could cause substantial competitive harm to the sponsor of the IND because a competitor could appropriate the information for use in its own IND or INDs. CBER regulations protect the confidentiality of IND submissions. Under 21 C.F.R. § 601.51, no data or information in a CBER IND file is available for public disclosure before FDA approves a biologics license application (BLA) for the product in the IND. The Exemption 4 documents in the *Vaughn* Index either are a part of the IND "G" file or contain data or information that is taken from the IND "G" or other xenotransplantation IND files. No xenotransplantation products (including IND "G") have approved BLA's. Thus, CBER cannot disclose any data or information that is in the IND "G" file or other xenotransplantation IND files, even if the documents containing that data or information are not themselves part of the file.
>
> 10. Exemption 5 of FOIA protects inter-agency or intra-agency documents "which would not be available by law to a party other than an agency in litigation with the agency." 5 U.S.C. § 552(b)(5). Included in Exemption 5 is the deliberative process privilege, which protects information that is pre-decisional and deliberative. The documents in the index for which ALFOI has asserted Exemption 5 are confidential internal letters, e-mails, memoranda, and drafts of CBER guidances and rules, which reflect FDA's internal deliberative decision-making processes concerning the testing and approval of new biologics products. The documents contain pre-decisional

For instance, paragraph nine does not indicate which documents contain trade secrets and which contain confidential commercial information. Pl.'s Reply at 10; 2d Banks Decl. ¶ 9. Yet the differentiation between the two is crucial, since each category has a different legal standard. Pl.'s Reply at 10; *compare Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1289 (D.C. Cir. 1983) (discussing the standard for trade secrets) *with Critical Mass Energy Project v. Nuclear Regulatory Comm'n*, 975 F.2d 871, 878-79 (D.C. Cir. 1992) (describing the standard for confidential commercial information).

Likewise, paragraph ten, which provides a cross-reference for more than 70 percent of all of the documents in the two *Vaughn* indices, states that the cross-referenced items are "confidential internal letters, e-mails, memoranda, and drafts of CBER guidance and rules, which reflect FDA's internal deliberative decision-making processes concerning the testing approval of new biologics products." Pl.'s Mot. for Summ. J. at 35 (*quoting* 2d Banks Decl. ¶ 9). This statement never explains why the documents are exempt; it only makes the conclusory statement that these documents automatically qualify for a FOIA exemption. Such conclusory statements are contradictory to the purpose of the *Vaughn* index. As this circuit has explained:

> Specificity is the defining requirement of the *Vaughn* index and affidavit; affidavits cannot support summary judgment if they are "conclusory, merely reciting statutory standards, or if they are too vague or sweeping." To accept an inadequately supported exemption claim "would constitute an abandonment of the trial court's obligation under the FOIA to conduct a *de novo* review."

King, 830 F.2d at 219 (footnotes omitted).

> opinions and/or recommendations of FDA personnel, and disclosure of the withheld documents would discourage the frank exchange of opinions and recommendations among such individuals. Disclosure, therefore, would be harmful to the deliberative process within FDA.

2d Banks Decl. ¶¶ 9-10.

Without a proper *Vaughn* index, a requester cannot argue effectively for disclosure and this court cannot rule effectively. *King*, 830 F.2d at 225. Rather than rule on the basis of inadequate *Vaughn* indices, the court orders FDA to submit new representative *Vaughn* indices with proper detailed document descriptions and reasons for withholding that illuminate the contents of the documents and the reasons for nondisclosure. *Id.* at 225-26. While the court understands that these requirements are an administrative burden on the agency, any lesser standard of compliance would not satisfy this circuit's requirements and FOIA's policy "in favor of the fullest possible disclosure of government records." *Founding Church of Scientology*, 603 F.2d at 949. Accordingly, the court rules that FDA's *Vaughn* indices are inadequate and FDA must submit new *Vaughn* indices.

IV. CONCLUSION

For the reasons stated above, the court grants in part FDA's and denies in part CRT's motions for summary judgment, in that the court determines that FDA's search was adequate. The court also grants in part CRT's and denies in part FDA's motions for summary judgment in part, in that the court determines that FDA's *Vaughn* indices are inadequate. As the indices are inadequate, the court cannot at this time consider whether information was properly withheld according to the FOIA exemptions. Finally, the court orders FDA to submit new sample *Vaughn* indices by November 10, 2002.[11] Each of the two new indices must be contained in a single document.

The court also orders the parties to renew settlement discussions. To the extent that the parties can reach agreement regarding the production or withholding of additional

[11] In the Joint Stipulation and Order entered by the court on December 20, 2001, the court instructed FDA and CRT to exclude any documents relating to any Novartis INDs from the *Vaughn* indices. Joint Stip. and Order at ¶ 4. This order also applies to the FDA's submission of new *Vaughn* indices.

documents, FDA need not include those documents in the new indices. If necessary, the court will issue a briefing schedule for renewed motions for summary judgment, with page limits, that will address the remaining issue: whether any of the FOIA exemptions permit FDA to withhold information requested by CRT. An Order directing the parties in a manner consistent with this Memorandum Opinion is separately and contemporaneously executed this _____ day of September 2002.

Ricardo M. Urbina
United States District Judge

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CAMPAIGN FOR RESPONSIBLE TRANSPLANTATION, Plaintiff, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, Defendant, and CIRCE BIOMEDICAL, INC. *et al*., Defendant-Intervenors	Civil Action No.: 00-2849 (RMU) Document Nos.: 58, 62

ORDER

GRANTING IN PART AND DENYING IN PART THE PLAINTIFF'S AND DEFENDANT'S MOTIONS FOR SUMMARY JUDGMENT

For the reasons stated in this court's Memorandum Opinion separately and contemporaneously issued this ___ day of September 2002, it is

ORDERED that the plaintiff's and the defendant's motions for summary judgment are **GRANTED in part** and **DENIED in part**; and it is

FURTHER ORDERED that defendant file new *Vaughn* indices (each index shall be contained in one document) that are consistent with the attached Memorandum Opinion no later than November 10, 2002. To the extent that the parties can reach agreement regarding additional documents, FDA need not include those documents in the new indices; and it is

ORDERED that this case is referred to United States Magistrate Judge Kay for settlement discussions to begin no later than September 20, 2002; and it is

FURTHER ORDERED that Novartis' unopposed request for a ruling that, because none exist, no agency-generated records concerning Novartis shall be produced in response to the modified FOIA request is **GRANTED**.

SO ORDERED.

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Ricardo M. Urbina
United States District Judge

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